August 10, 2005

Stephen B. Kemp
Vice President
Occidental Chemical Corporation (OxyChem)
Occidental Towers
5005 LBJ Freeway
Dallas, TX 75244-6119

Dear Mr. Kemp:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dechlorane Plus posted on the ChemRTK HPV Challenge Program Web site on November 2, 2004. I commend Occidental Chemical Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that OxyChem advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
N. Patel
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Dechlorane Plus®

Summary of EPA Comments

The sponsor, Occidental Chemical Company (Oxychem), submitted a test plan and robust summaries to EPA for Dechlorane Plus® (1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene, CAS No. 13560-89-9) dated September 24, 2004. EPA posted the submission on the ChemRTK HPV Challenge Website on November 2, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitted data are adequate for the purposes of the HPV challenge program. The submitter needs to provide an estimated boiling point in the robust summary.

2. Environmental Fate. The submitted data for photodegradation and biodegradation are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide modeled fugacity data and consider whether the proposed stability-in-water test is necessary.

3. Health Effects. EPA reserves judgement on adequacy of the submitted data for acute and genetic toxicity endpoints pending submission of additional critical information in the robust summaries. The submitter needs to provide data from a combined repeated-dose/reproduction/developmental toxicity screening test.

4. Ecological Effects. While no adequate data were submitted for these endpoints, EPA believes that no further testing is needed for the purposes of the HPV Challenge Program because the physicochemical properties of Dechlorane Plus® suggest that measurable toxicity to aquatic organisms will not occur.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Dechlorane Plus® Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The submitted data for melting point, vapor pressure, water solubility, and partition coefficient are adequate for the purposes of the HPV challenge program.

Boiling point. No data were submitted. As the reported melting/decomposition point is 350 °C, this value may be reported for the boiling point, or the submitter may provide an estimated value derived from a vapor pressure or from a reduced-pressure boiling point. A robust summary is needed for the endpoint.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for photodegradation and biodegradation are adequate for the purposes of the HPV Challenge Program. The “Conclusion” section of the fate discussion does not correlate smoothly with the preceding data adequacy discussions.

Stability in water. The discussion in the test plan based on a photochemistry study is confusing. The submitter also needs to consider whether the proposed test is necessary. Although allylic chlorines (four in this case) are potentially water-labile, their bridgehead locations render them highly resistant to displacement. If a careful structural analysis indicates a lack of water-sensitive functional groups and hydrolysis is thus not expected to be an important fate process, the submitter needs to discuss this in the test plan and robust summary.

Fugacity. The submitted data for this endpoint are from a water-sediment absorption study. The submitter needs to provide fugacity results using the Level III Fugacity Model.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

EPA reserves judgement on the submitted data for the acute and genetic toxicity endpoints pending the submission of critical robust summary information.

Repeated-dose toxicity. The data submitted for the repeated-dose toxicity endpoint were generated at the Industrial Bio-test Laboratories and are thus considered inadequate by EPA. The submitter needs to provide data for this endpoint (see recommendation below for Reproductive/Developmental toxicity).

Reproductive/Developmental toxicity. EPA disagrees with the submitter's tiered approach in which testing for reproductive and developmental toxicity depends on the results of repeated-dose and genetic toxicity testing and a pharmacokinetic study. For the HPV Challenge Program, the submitter needs to provide adequate data for all endpoints. EPA recommends a combined repeated-dose/reproduction/ developmental toxicity screening test (OECD TG 422).

Ecological Effects (fish, invertebrates, and algae)

No data are available for invertebrate and algal toxicity endpoints and EPA disagrees with the submitter that adequate data exist for the fish acute toxicity endpoint (test concentrations were above the water solubility limit). However, EPA believes that no further testing is needed for the purposes of the HPV Challenge Program because the low water solubility and high log K_{ow} values of Dechlorane Plus® suggest that measurable toxicity to aquatic organisms will not occur.

Specific Comments on the Robust Summaries

Health Effects

General. The submitter needs to provide information on the test substance used in the studies and its purity. The robust summaries describe the test substance "as prescribed by 1.1 - 1.4". However, some of those sections are missing.

Acute toxicity. The missing study information (Ref. 11) includes test substance used and its purity, whether or not any clinical signs were seen, and whether necropsy was performed.

Genetic toxicity (gene mutation). The following critical information is missing in the robust summary (Ref. 14): test substance, its purity, solvent used, negative control (solvent/vehicle), medium, positive control responses to validate the study and criteria for study acceptability.

Genetic toxicity (cytogenetic assay). The following information is missing in the robust summary for mouse lymphoma assay: test substance, its purity, and concentrations used in the second definitive

study (precipitates were seen above 20 µg/mL in the initial assay–the listed concentrations in the robust summary are up to 150 µg/mL).

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.